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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,692	01/11/2002	Thomas R. Cech	015389-002640US	3439

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,692	CECH ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *October 6, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *25 and 71-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *25 and 71-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The Amendment filed October 3, 2006 in response to the Office Action of April 21, 2005 is acknowledged and has been entered. Previously pending claims 1-24 and 26-70 have been cancelled, claim 25 has been amended and new claims 71-78 have been added. Claims 25 and 71-78 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4 Claim 25 remains rejected and newly added claims 74-78 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed April 21, 2005, section 9, pages 9-12.

It is noted that the limitation "consisting essentially of" is interpreted to mean "comprising" because MPEP, 2111.03 defines the phrase "consisting essentially of" as limiting the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). Since it is clear that the addition of undefined amino acids would not materially affect the basic and novel characteristic(s) of the nucleic acid encoding the claimed 10 mer, it is appropriate to interpret the phrase as comprising.

Applicant argues that (1) in the new claims, the polynucleotide sequences and the polypeptides they encode are defined by the disclosure of SEQ ID NO:1 and SEQ ID NO:2, fragments, variants etc, (2) the immune function is now defined since it is specific and correlated to the disclosure structure of the hTRT sequence, (3) the function is particular to the subject matter claimed and is not

applicable to a broad class of invention and such functional descriptions of genetic material meet the written description requirement if "coupled with a known or disclosed correlation between function and structure", (4) given the disclosure of the entire polynucleotide sequence encoding and the entire amino acid sequence coupled with a disclosed correlation between the function and the disclosed structure, one can envision the structure of the claimed compositions by the combination of structure and function (5). The arguments have been considered but have not been found persuasive because although Applicant has indeed disclosed the entire polynucleotide sequence encoding and the entire amino acid sequence coupled with a disclosed correlation between the function and the disclosed structure, one cannot envision the structure of the claimed nucleic acids in the compositions by the combination of structure and function because the specification provides no teaches drawn to the structure of nucleic acids encoding the claimed proteins which consist of or comprise immunogenic fragments, that is which encoded fragments are immunogenic and the specification provides no structure of at least 10 contiguous amino acids of SEQ ID NO:2 that when administered to a subject elicits an adaptive immune response against SEQ ID NO:2 and no teaching of the structure of the nucleic acid encoding said 10mer.

Applicant further argues that Lilly is not applicable to the pending claims because (1) the entire hTRT gene has been disclosed and the hTRT protein cloned and characterized in detail, (2) the present claims do not define a genus of nucleic acids by function but rather by a combination of structure and function correlated with that function, (3) to the extent that the present claims are drawn to "comprising" language, one of skill in the art can easily envisage a number of

representative examples of sequences that could be present. The argument has been considered but has not been found persuasive because although the full length sequences are known and one would immediately envision that the full length sequence will elicit an adaptive immune response against SEQ ID NO:2 when administered to a subject, the same cannot be said for the claims as currently constituted which read on undefined fragments encoded by the claimed nucleic acids wherein no correlation has been made between structure and the specific function of eliciting an adaptive immune response specific for SEQ ID NO:2. Finally, although one can easily envisage a number of representative examples of the sequences that could be present, the specification does not provide adequate information as to which fragments, encoded 10mer structures have the function claimed.

Applicant argues that the specification discloses a common structural feature shared by members of the claimed genus which constitutes a substantial portion of the genus and one can readily envisage nucleic acid sequences that encode SEQ ID NO:2 and although there may be substantial variability, the necessary basic element remains because SEQ ID NO:2 may be combined with sequences known in the art, but the necessary common attribute is the polynucleotide encoding SEQ ID NO:2. The arguments have been considered but have not been found persuasive because applicant is arguing limitations not recited in the claims as currently constituted. The claims are not drawn to nucleic acid sequences that encode SEQ ID NO:2, the claims are drawn to nucleic acid sequences that encode fragments of SEQ ID NO:2 which when administered to a subject elicit an adaptive immune response to SEQ ID NO:2. Thus, the variability remains and the specification teaches only nucleic acid encoding SEQ ID NO:2 and this nucleic

acid clearly does not constitute a substantial portion of the genus since the genus is drawn to a whole multitude of nucleic acids encoding fragments wherein the specification does not provide sufficient information drawn to the structure that functions to elicit an adaptive immune response against SEQ ID NO:2 when administered to a subject.

Applicant argues that to find that an applicant is required to disclose every example of a flanking sequence which the claims might encompass would be an impossible and unreasonable burden at odds with current written description. The argument has been considered but has not been found persuasive because the previous rejection was drawn not only to flanking residues and to nucleic acids encoding polypeptides "comprising" but was also drawn to claim 25 which, at the time the last action was written, was drawn to "nucleic acid encodes a chimeric protein consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ. ID NO:2 fused with an amino acid sequence of another protein", wherein Examiner specifically states in the prior action that the claimed invention encompasses a substantial variety of subgenera, that given the undefined and apparently unlimited nature of the claimed polynucleotides, it is apparent that the immunogenic functions of the polypeptides are both unknown and highly varied. Although the claims have been somewhat narrowed, the claims are still drawn to polynucleotides encoding polypeptides whose immunogenic functions are unknown and are highly varied. Further Examiner specifically stated that there is no description of the conserved regions which are critical to the structure and function of the genus claimed, that is an immunogenic composition comprising said polynucleotides. There is no description of the sites at which variability may be tolerated and there is no information regarding the

relation of structure to function. Finally, given that the prior art of record does not provide compensatory structural or correlative teachings sufficient to enable one of skill to identify the polynucleotides encompassed, one would reasonably conclude that the invention was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention. Thus the claimed invention is not adequately described and the claims as currently constituted do not satisfy the written description requirements of 112, first paragraph.

5. Claim 25 remains rejected and newly added claims 71-78 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed April 21, 2005, section 8, pages 8-9.

Because Applicant did not distinctly and specifically point out the supposed errors in the rejection, the rejection of claim 25 is maintained and claims 71-78 are rejected under 35 USC 112 first paragraph for the reasons previously set forth.

Double Patenting

6. Claim 25 remains rejected and newly added claims 71-78 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed April 21, 2005 sections 12 and 13, pages 13-16.

Applicant states that upon indication of allowed claims, Applicant will provide terminal disclaimers to resolve double-patenting rejections, if appropriate. The rejection stands.

New Grounds of Rejection

Claim Rejections - 35 USC 112

7. Claim 25 is rejected are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a fragment of SEQ ID NO;2 fused to another amino acid sequence that enhances an adaptive immune response to said fragment has no clear support in the specification and the claims as originally filed. Applicant points to support for the newly added limitation at page 37, lines 3-23. However, a review of page 37, lines 3-23 reveals only support for a fusion protein wherein "The invention further provides hTRT polypeptides that are modified, relative to the amino acid sequence of SEQ. ID. NO: 2, in some manner, e.g., truncated, mutated, derivatized, or fused to other sequences (e.g., to form a fusion protein)". The suggested support has been considered but has not been found persuasive because there is no teaching drawn specifically to amino acid sequences that enhance an adaptive immune response. The subject matter claimed in claim 25 broadens the scope of the invention as originally disclosed in the specification. It is noted however that the specification at paragraph 0204 of the published application is drawn to "Short stretches of hTRT protein amino acids may be fused with those of another protein, such as keyhole limpet hemocyanin, and an anti-hTRT antibody produced against the chimeric molecule." Thus amendment of the claim to recite fusion to KLH protein which is a known protein that enhances adaptive immune response would obviate the instant rejection.

8. Claim 73 is rejected are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a composition containing a nucleic acid that encodes a

polypeptide comprising a sequence at least 98% identical to the 1132 residues of SEQ ID NO:2, wherein the composition elicits an adaptive immune response against hTRT when administered to a subject has no clear support in the specification and the claims as originally filed. Applicant points to support for the newly added limitation at page 37, lines 3-23. However, a review of page 37, lines 3-23 reveals only support for a variants of SEQ ID NO:2 and does not disclose compositions containing a nucleic acid that encodes a polypeptide comprising a sequence at least 98% identical to the 1132 residues of SEQ ID NO:2, wherein the composition elicits an adaptive immune response against hTRT when administered to a subject. Applicant further points to page 148 lines 3-6 which defines substantial identity as identity that includes "at least about 98%" identity. However, there is no nexus between this definition and the generally discussed variants and there is no nexus between either of these two citations and the newly added claim drawn to a composition containing a nucleic acid that encodes a polypeptide comprising a sequence at least 98% identical to the 1132 residues of SEQ ID NO:2, wherein the composition elicits an adaptive immune response against hTRT when administered to a subject. The subject matter claimed in claim 73 broadens the scope of the invention as originally disclosed in the specification.

9. Claims 71-78 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a composition containing a nucleic acid that encodes a polypeptide SEQ ID NO:2, a fragment thereof, a sequence at least 98% identical to the 1132 residues of SEQ ID NO:2, wherein the composition elicits an adaptive immune response against hTRT when administered to a subjects has no clear support in

the specification and the claims as originally filed. Applicant points to support for the newly added claim limitations drawn to said compositions at page 90, lines 3-8. The citation has been considered but has not been found persuasive because a review of the citation has been revealed support only for "An immune response can also be raised by delivery of plasmid vectors encoding the polypeptide of interest (i.e., administration of "naked DNA")." In the absence of a limitation drawn to plasmid vectors/naked DNA the newly added claims are drawn to new matter. The subject matter claimed in claims 71-78 broadens the scope of the invention as originally disclosed in the specification.

10. No claims allowed.

11. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar
Primary Patent Examiner
January 4, 2007